



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,685	11/12/2003	James F. McGuckin JR.	1238DIV	7009

7590
NEIL D. GERSHON
REX MEDICAL
1011 HIGH RIDGE RD
Stamford, CT 06905

11/28/2007

EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
----------	--------------

3774

MAIL DATE	DELIVERY MODE
-----------	---------------

11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/706,685

Applicant(s)

MCGUCKIN ET AL.

Examiner

Ann Schillinger

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/4/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Frazier et al. (US Pat. No. 6,231,561). Frazier et al. discloses a vascular device that is expandable to three different diameters, comprising vessel engaging members (90) and a valve. The vessel engaging members further include penetrating tips (96). The vessel engaging members will pull the internal wall of the vessel radially inwardly. Please see col. 4, lines 6-41; col. 8, lines 18-48; and col. 9, line 58 through col. 11, line 20. The device also has a substantially conical shape as shown in Figure 3A, element 36.

Claims 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Bessler et al. (US Pat. No. 5,855,601). Bessler et al. discloses a valve (35) with a support structure (32) and a longitudinal axis drawn off-center through the middle of the structure. The valve has a substantially conical configuration and it extends distally beyond a distal end of the support structure (lower end of Figure 4) and the support structure distal end is proximal to a distal portion of the valve. As the valve portion stretches across the support structure it is also

connected to the proximal end of the support structure. The support structure's cylindrical form can further be seen in Figures 4 and 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Flomenbilt et al. (US Pat. No. 5876434). Frazier et al. discloses the invention substantially as claimed, however, Frazier et al. does not disclose the use of shape memory material with exposure to body temperature to control the alterations of the device. Flomenbilt et al. teaches an implantable medical device that uses shape memory material and exposure to body temperature in col. 2, lines 37-65 and col. 4, line 66 through col. 5, line 15 for the purpose of causing the device to assume the necessary configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shape memory material with exposure to body temperature in order to cause the device to assume the necessary configuration.

Claims 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Vazquez et al. (US Pat. No. 6,287,339). Frazier et al. discloses the invention substantially as claimed, however, Frazier et al. does not disclose specific details about the structure of the artificial heart valve that may be implanted. Vazquez et al. teaches a heart valve prosthesis with a reinforcement ring, duckbill configuration, and an offset configuration at a

proximal area of a vascular device in Figures 2, 6, and 8, and in columns 6-8 to act as a permanently implantable abutment structure which will assist weakened or diseased heart valves. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to the heart valve of Vazquez et al. in order to create a prosthetic heart valve that will assist a weakened or diseased heart valve.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Wilson et al. (US Pat. No. 6053896). Frazier et al. discloses the invention substantially as claimed, however, Frazier et al. does not disclose the use of blood drainage openings in the valve. Wilson et al. teaches a ventricular heart valve with these openings in col. 2, lines 42-65 and col. 3, line 66 through col. 4, line 7 for the purpose of relieving excess pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these openings in order to relieve excess pressure.

Claims 12, 15, 16, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Andersen et al. (US Pat. No. 5,840,081). Frazier et al., as described above, discloses the invention substantially as claimed, however, Frazier et al. does not disclose using a balloon catheter with the prosthesis. Andersen et al. teaches a heart valve prosthesis used with a balloon catheter in col. 4, lines 11-35 for the purpose of properly implanting the valves in their desired locations. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a balloon catheter in order to properly implant the valves in their desired locations.

Andersen et al. discloses claim 15 in col. 4, lines 66-67 and col. 5, lines 28-56.

Andersen et al. discloses claim 16 in col. 6, lines 20-21.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Anderson et al. in further view of Flomenbilt et al. (US Pat. No. 5876434). Frazier et al. and Anderson et al. disclose the invention substantially as claimed, however, they do not disclose the use of shape memory material with exposure to body temperature to control the alterations of the device. Flomenbilt et al. teaches an implantable medical device that uses shape memory material and exposure to body temperature in col. 2, lines 37-65 and col. 4, line 66 through col. 5, line 15 for the purpose of causing the device to assume the necessary configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shape memory material with exposure to body temperature in order to cause the device to assume the necessary configuration.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frazier et al. in view of Andersen et al. in further view of Wilson et al. (US Pat. No. 6053896). Frazier et al. and Andersen et al. disclose the invention substantially as claimed, however, they do not disclose the use of blood drainage openings in the valve. Wilson et al. teaches a ventricular heart valve with these openings in col. 2, lines 42-65 and col. 3, line 66 through col. 4, line 7 for the purpose of relieving excess pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these openings in order to relieve excess pressure.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. in view of Wilson et al. (US Pat. No. 6053896). Bessler et al. discloses the invention substantially as claimed, however, Bessler et al. does not disclose the use of blood drainage openings in the valve. Wilson et al. teaches a ventricular heart valve with these openings in col. 2, lines 42-65 and col. 3, line 66 through col. 4, line 7 for the purpose of relieving excess pressure. Therefore,

it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these openings in order to relieve excess pressure.

Response to Arguments

Applicant's arguments with respect to claims 1-17 and 25-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
10/706,685
Art Unit: 3774

Page 7

Ann Schillinger
November 24, 2007



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700